

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 23-1332 (MN)
)	(Consolidated)
HETERO USA, INC.,)	
HETERO LABS LIMITED,)	
HETERO LABS LIMITED UNIT-V,)	
AUROBINDO PHARMA USA, INC.,)	
AUROBINDO PHARMA LTD.,)	
SANDOZ INC., and SUN)	
PHARMACEUTICAL INDUSTRIES, LTD.,)	
)	
Defendants.)	
_____)	
ABBVIE INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 24-1254 (MN)
)	
HETERO USA, INC.,)	
HETERO LABS LIMITED,)	
HETERO LABS LIMITED UNIT-V,)	
HOSTER LABS PRIVATE LIMITED,)	
AUROBINDO PHARMA USA, INC.,)	
AUROBINDO PHARMA LTD.,)	
SANDOZ INC., SANDOZ PRIVATE)	
LIMITED, SANDOZ GMBH, and SUN)	
PHARMACEUTICAL INDUSTRIES, LTD.,)	
)	
Defendants.)	

STIPULATION AND [PROPOSED] ORDER

The Court, upon the consent and request of Plaintiff AbbVie Inc. (“Plaintiff”) and Defendant Sandoz Inc. (“Sandoz”), hereby acknowledges the following Stipulation and issues the following Order in the above-captioned actions.

STIPULATION

1. This Court has subject matter jurisdiction over these patent infringement actions (the “Actions”) and personal jurisdiction over Plaintiff and Sandoz for purposes of the Actions.

2. Venue is proper in this Court as to Plaintiff and Sandoz for the Actions.

3. Plaintiff has asserted claims against Sandoz for infringement of U.S. Patent Nos. RE47,221, 8,962,629, 9,951,080, 10,981,923, 11,186,584, 11,661,425, 11,680,069, 11,718,627, 11,198,697, 9,963,459, 10,519,164, 10,981,924, 10,597,400, 11,535,624, 11,773,105, 11,780,847, 11,787,815, 11,795,175, 9,879,018, 12,077,545, 12,103,933, 12,110,297, 12,110,298 (together, “the Asserted Patents”) in connection with Sandoz’s submission of Abbreviated New Drug Application (“ANDA”) No. 218792 directed to generic upadacitinib extended release tablet products (15 mg, 30 mg, 45 mg) to the U.S. Food and Drug Administration (“FDA”) (“Sandoz ANDA Products”).

4. For the purposes of the Sandoz ANDA Products only, Sandoz admits that the Asserted Patents are enforceable, valid, and would be infringed by the commercial manufacture, use, and/or sale within the United States of the generic upadacitinib extended release tablet products (15 mg, 30 mg, 45 mg) that are the subject of the Sandoz’s ANDA No. 218792.

5. Sandoz admits that the submission of ANDA No. 218792 to the FDA for purposes of obtaining regulatory approval to engage in the commercial manufacture, use, and/or sale within the United States of generic upadacitinib extended release tablet products (15 mg, 30 mg, 45 mg) was an act of infringement of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A).

6. The parties agree that all other claims, counterclaims, and defenses asserted against each other in Plaintiff’s and Sandoz’s pleadings in the Actions, including the allegations and averments contained therein, should be dismissed, without prejudice.

ORDER

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Plaintiff and Sandoz, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. The filing of ANDA No. 218792 was an act of infringement of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A).

2. All other claims, counterclaims, and defenses asserted by the parties against each other in Plaintiff's and Sandoz's pleadings in the Actions, including the allegations and averments contained therein are hereby dismissed, without prejudice.

3. Absent a license agreement or other authorization by Plaintiff, Sandoz, its officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, the generic upadacitinib extended release tablet products (15 mg, 30 mg, 45 mg) described by ANDA No. 218792 during the life of the Asserted Patents, including any extensions and pediatric exclusivities thereof.

4. Plaintiff and Sandoz each expressly waive any right to appeal or otherwise move for relief from this Stipulation And Order.

5. This Court retains jurisdiction over Plaintiff and Sandoz for purposes of enforcing this Stipulation And Order.

6. This Stipulation And Order shall finally resolve the Actions between the Parties.

7. This Stipulation And Order is without prejudice to any claim, defense, or counterclaim in any possible future actions between Sandoz and Plaintiff regarding the Asserted Patents and a product other than generic upadacitinib extended release tablet products (15 mg, 30 mg, 45 mg) described by ANDA No. 218792.

8. Nothing in this Stipulation and Order prohibits Sandoz from maintaining Paragraph IV certifications to the Asserted Patents for the purpose of receiving or maintaining final FDA approval of ANDA No. 218792.

9. The Clerk of the Court is directed to enter this Stipulation And Order forthwith in the Actions.

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Attorneys for Plaintiff AbbVie Inc.

April 11, 2025

SO ORDERED:

This _____ day of _____, 2025.

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HONORABLE MARYELLEN NOREIKA
UNITED STATES DISTRICT JUDGE